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Ethical control of researches whose results offer high risk to the health of the population

Controle ético de pesquisas cujos resultados tenham alto risco para a saúde da população

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ABSTRACT This article discusses the emergence of ethical conflicts between the need to ensure the advances in science and the need to control their possible consequences for humanity. A research was carried out to analyze the scientific Latin-American literature and the Brazilian legal and regulatory bases on the ethical regulation of researches that do not involve humans as subjects of the intervention, and found the absence of norms for the regulation of such researches and the lack of scientific literature on the subject. Considering the severity of the impact that certain researches may cause to the health of the population, the conclusion is that there is the need to establish strong measures for their ethical control.

KEYWORDS Ethics in research. Bioethical issues. Codes of ethics.

RESUMO Este artigo problematiza o conflito ético surgido entre a necessidade de garantir o avanço da ciência e controlar suas possíveis consequências para a humanidade. Em pesquisa realizada na literatura científica latino-americana e nas bases jurídicas e normativas brasileiras sobre a regulamentação ética de pesquisas que não envolvem seres humanos como sujeitos da intervenção, constataram-se tanto a ausência de normatização para a regulação ética de tais pesquisas quanto a incipiência da produção científica acerca do tema. Devido à gravidade do impacto que determinadas pesquisas podem causar à saúde da população, conclui-se pela necessidade de estabelecer fortes medidas para seu controle ético.

PALAVRAS-CHAVE Ética em pesquisa. Temas bioéticos. Códigos de ética.

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Introduction

In Brazil, the national ethics control system for researches involving human beings has already been consolidated. However, there are researches not directly related to the human being as the subject of the scientific intervention, but the results of which may cause a high risk impact on the health of the population. In this sense, it is necessary to discuss whether researches whose results imply in high risks for the health of the population should be previously assessed. Or, still, whether researchers, institutions and other stakeholders involved in those studies should be made ethically responsible for undue or undesired consequences.

According to the Universal Declaration on Bioethics and Human Rights (UDBHR), adopted by the United Nations Educational, Scientific and Cultural Organization (Unesco) in 2005, the freedom of scientific research must respect human dignity, human rights and fundamental freedoms, and also “safeguard and promote the interests of present and future generations” (UNESCO, 2005).

Drawing on this premise, this article discusses the ethical conflicts arising from the need to ensure the advances in science and, at the same time, control their possible consequences for humanity. With the purpose of serving as elements for the analysis, the article presents and discusses the results of a research on the scientific Latin-American literature and on the legal and regulatory bases of the ethical regulation of researches that do not involve humans as subjects of the intervention.

Background

In the modern era, scientific research no longer seeks knowledge for the sake of knowledge and; it seeks knowledge mainly for its practical and instrumental application (HORKHEIMER, 2003). This paradigm brought

great advances in the areas of biology and life sciences. However, beyond the intrinsic factors of science, there are several sanitary, social, political and economic factors that influence the conduct of researches and that range from the choice of the study object to the practical application of the results.

In this context, an important aspect to be considered when carrying out research is the impact of their results on the health of the population. In this regard, Garrafa (1998, p. 99) expresses that:

The advances achieved by scientific and technological development in the fields of biology and health, especially in the last thirty years, has been putting humanity in situations that until recently were unimaginable. [...] If on the one hand all these achievements raise hope of better quality of life, on the other hand, they create a number of contradictions that need to be responsibly analyzed aiming at the balance and wellbeing of the human species and life on this planet.

In the same sense, Schramm (1998, p. 217) considers that the advances achieved in the area of biotechnoscience are, at the same time, “[...] motives for great hopes and anguish, consensus and conflicts, especially, of a moral kind”.

What derives from these considerations is the difficulty to determine the ideal threshold of the commitment between scientific freedom and the legitimate concerns about the safety and interests of the population, which constitutes a great ethical challenge for the scientific community. Evaluating whether the advances in science and technology may bring eminent or future risks for humanity involves issues of various magnitudes, which range from technical aspects of the issue to moral themes related to it. As a premise, it is recognized that scientific researches – even though they may bring harmful consequences to human beings – should not be rejected a

priori, but their applications must be ethically controlled (CRUZ; OLIVEIRA; PORTILLO, 2010).

In Brazil, the National Health Council (CNS) (CNS, 2014) has as its mission the deliberation, surveillance, follow-up and the monitoring of public policies in health established in the sphere of the Unified Health System (SUS). In 1996, by means of Resolution nr 196, CNS approved the regulatory guidelines and standards for researches involving human beings and created the National Research Ethics Commission (Conep), which has as its main attribution the review of ethical aspects of researches involving human beings. As its mission, Conep develops and updates guidelines and standards for the protection of subjects of research and coordinates the network of Research Ethics Committees (RECs) of institutions. In 2012, Conep carried out a review of those guidelines, resulting in the Resolution nr 466, of 12th December 2012, which is in force. In this sense, all research projects involving human beings in Brazil are subject to the appreciation of this unified model of ethical review by the CEP-Conep system.

However, there are researches that do not directly involve human being as the object of the scientific intervention, but whose results may have a high risk impact on the health of the population, which points out to the need of reflection on the ethical control of those studies as well.

An example of this problematic is a research carried out in Holland, published in 2012, which provoked/induced mutations that altered the transmissibility of *Influenza A* virus, subtype H5N1 (bird flu), among mammals (BIOLOGICAL WEAPONS CONVENTION, 2012). The implications of carrying out and making public the results of this research had great repercussion in the scientific community, civil society, health organizations and international instruments, such as the Biological

Weapons Convention (UNOG, 2014). The last-named raised the debate on the need of mechanisms for the assessment of risk in researches – especially those that are not regulated by the traditional normative instruments already in existence and related to ethics in research involving human beings – and the creation of codes of conduct for researchers.

Besides the concern about the possibility of it being used as war weapon, the research involving H5N1 also generated doubts regarding its impact on the health of the population, in case of an accidental or even an intentional dispersion of the ‘new’ subtype of the virus, or even an organism with new characteristics, capable of causing severe and imponderable consequences, such as new outbreaks, epidemics and even pandemics.

This kind of research refers not only to technical biosafety issues but also to the broad biological safety issues – strategic and greatly important for the sanitary control and defense of any State – as well as to the ethical issues involved.

Drawing on an ethical perspective, this example expands the initial issues presented in this article: Researches that do not directly involve human beings should be previously reviewed by external commissions? Should the ones involved in these researches be made ethically responsible for undue or undesired consequences? How to balance the guarantee of freedom for scientific production and the protection of the populations’ health?

Based on these reflections, this work brings to the sphere of Bioethics the discussion about the responsibilities of researchers, research institutions, funders, and States regarding the risks and harm to populations related to carrying out researches that do not involve human beings as subject of scientific experiment.

Material and methods

In order to substantiate the reflection and the discussion about the problematic presented in this article, a systematic search was carried out on the Brazilian literature on the ethical debate of researches that do not involve human beings. The data bases searched were the Scientific Electronic Library Online (SciELO) and the Latin-American and the Caribbean Literature in Health Sciences (Lilacs), making use individually of the following descriptors: ethics in research; biomedical themes; and codes of ethics. Considering the proximity between the Brazilian and Latin-American social and institutional realities, the literature searching also considered the academic production of the region with the objective of better informing the analysis of the national regulatory framework.

The articles included in the study were those published on journals in their integrity; thus, the study did not include books, book reviews, editorials, and publications other than articles, as well as full works not available on-line.

Searches were also carried out on the Brazilian regulation with which researches that do not involve human beings must comply. The research platforms were: Senado Federal (Federal Senate), available at: <<http://www25.senado.leg.br/web/atividade/legislacao>>; Portal da Legislação (Legislation Portal),

available at: <<http://www4.planalto.gov.br/legislacao>>; and Saúde Legis (Health Legislation System): <http://portal2.saude.gov.br/saudelegis/LEG_NORMA_PESQ_CONSULTA.CFM>, besides the open sources: <<http://www.cnpq.br/>>, <<http://portal.fiocruz.br/pt-br>> and <<https://www.google.com.br/>>. The descriptors used were: ethical control, research ethics, high risk research, and codes of ethics.

The material was selected, analyzed, and discussed in the light of the normative referential of the Universal Declaration on Bioethics and Human Rights.

Results and discussion

After applying the filter by thematic area, the titles and abstracts of 853 articles initially identified were analyzed, with the objective of excluding those that addressed ethical aspects in researches involving human beings, animals or observational, in order to restrict the literature to works that actually deal with the control of researches that do not use human beings as subject of scientific intervention. This stage, in which repeated works and those that are not full articles published on journals were excluded, resulted in the selection of a total of 18 articles, as shown on *table 1*.

Table 1. Selected articles

Title	Approaches and Considerations
1. Tecnologia, Aids e ética em pesquisa (SCHEFFER, 2000).	Discussion on ethics in research with human beings, using the example of multicenter studies of antiretroviral therapy for HIV in developing countries.
2. Pensamientos de Juan de Dios Vial Correa en torno a: los problemas éticos en ciencia e investigación (CORREA, 2004).	Special edition of journal comprising articles on issues such as: ethics of Medical Act, human embryo statute, human genome and cloning.
3. A responsabilidade do pesquisador ou sobre o que dizemos acerca da ética em pesquisa (PADILHA ET AL., 2005).	Ethics in Nursing. Refers to the use of scientific research for destructive purposes. But the main approach is on studies involving human beings.

Table 1. (cont.)

4. A ética na pesquisa e a epistemologia do pesquisador (RIOS, 2006).	Broad discussion on ethics in sciences in general, not focusing on or describing any kind of research.
5. A produção científica e a ética em pesquisa (MIRANDA, 2006).	Discusses the Free and Informed Consent Form in the protocols of research involving human beings and the qualification of the Research Ethics Centers.
6. Reflexiones éticas sobre la investigación científica en Biomedicina desde el prisma de la Universidad Médica (CANO, 2006).	Addresses ethical reflections on all types of research. But the focus is on researches involving human beings.
7. Conocimientos de la ética de la investigación científica (HERNÁNDEZ ET AL., 2008).	Reports a study conducted at the Faculty of Medical Sciences of Havana to access the knowledge of professionals on ethics in research involving human beings.
8. Ética e pesquisa (NOSELLA, 2008).	Extensively addresses research ethics, in all fields of knowledge, with historical philosophical fundaments of the relation between research activities and moral obligations, throughout history.
9. Ética e Investigación Científica en la Sociedad Globalizada (NORERO; TORO; CONTERERAS, 2009).	Discusses ethical control in scientific research broadly. Concludes on the importance of ethics in professional societies and the need to develop an 'ethics for the future' concerned about the new generations and their sustainability.
10. Aspectos Éticos y Legales de La Investigación Científica en Brasil (SILVA; BARRERA GARCÍA; SILVA, 2010).	Survey on the ethical regulatory process of scientific research in Brazil. In the article there is no mention to researches whose results have impact on the health of the population.
11. Las investigaciones biotecnológicas. Implicaciones éticas y sociales (DIAGO ET AL., 2010).	Analyses the social impact of biotechnology applied in humans, focusing on genetics therapy and the human genome project.
12. O papel da plausibilidade na avaliação da pesquisa científica (ALMEIDA, 2011).	Addresses methodological issues, such as: Hypothesis test. Reproducibility of tests. Statistical methods and procedures.
13. Retos de la bioética frente a la biotecnología. Necesidad de la educación en bioética (RESTREPO, 2011).	Addresses bioethics education, pointing to the need of bioethics education with anthropological premises that respect the human being.
14. Ética em Pesquisa: antigos conhecidos, novos desafios (COSTA, 2013).	States that in the Research Ethics Committees for researches involving human beings, research ethics should not be seen as bureaucracy to fulfill certain criteria or fill-in official forms, but as an utmost necessary agenda, completing in a crucial way the vast framework of functions that embrace the principle of respect for the integrity of all beings.
15. Interconexão entre Direito e bioética à luz das dimensões teórica, institucional e normativa (CARREIRO; OLIVEIRA, 2013).	Verifies that bioethics may help the Judicial Branch and the Law enforcer to make compatible judicial rationality and ethical reflection provided by new scientific paradigms. Cites in the introduction the techno-scientific advances and issues resulting from the unsafety generated by the human destructive capacity, but broadly and not specifying the research results.
16. Normas de bioética para una investigación científica (AMATRIAIN ET AL., 2013).	Discusses the compliance with bioethical regulations in studies involving human beings, focusing on the use of "Double Standard".
17. Una mirada filosófica a la ética de la investigación (LABOY, 2013).	Questions the frauds in researches and the ethical conduct in researches involving human beings. Considers that the codes of ethics in researches have been inefficient for many scientists. Concludes for the need of a philosophical reflection of ethics and moral in research.

Table 1. (cont.)

18. Quality perception in research laboratories from FIOCRUZ after QMS implementation (PRESOT ET AL., 2014).	Describes the perception of collaborators after the implementation of the Quality System in a research laboratory. As a result, biosafety, training and ethics were considered the most important parameters.
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The analysis of the material indicated that many articles (1-3-5-6-7-14-16) addressed researches involving human beings, even though the titles or abstracts did not point out this characteristic. Some articles addressed themes such as research with embryonic stem cells or cloning (2-11), while others treated the theme of research ethics in a broader and more generalized view (4-8-9-17), not focusing on the problematic of studies that do not involve human beings directly, but whose results may imply impacts on the health of the population.

Although this result indicates that the discussion on the ethical control of this type of research is rather incipient, giving the impression that the issue still passes unnoticed by the scientific community, it is possible to find some articles that address the theme of the researchers' responsibility in the scientific practice, from a broader or indirect perspective, and that should be highlighted.

Laboy (2013), for example, analyzed several incidents in which frauds permeated the scientific investigation, advocating the need to discuss research ethics from a philosophical posture. Norero, Toro and Contreras (2009), in another example, discussed the importance of ethics in professional societies and the need to develop an 'ethics of the future' concerned with the new generations and their sustainability. All the authors questioned whether there are effective instances of ethical control in researches and in the application of new knowledge. Complementarily, Rios (2006) problematized the objectives, methods and results of researches in all areas of knowledge, pointing out the need to consider ethics

in the scientific practice not only in order to impose limits to the studies, but also to improve the quality of the researches.

On the other hand, the search carried out on the Brazilian normative and legal bases did not indicate any norm or regulation directly related to the theme, but only to the ethical control of researches involving human beings and animals, besides the codes of ethics of the various professional categories and of institutions. This aspect confirms the results reported by Silva, Barrera-García and Silva (2010) in a survey of the regulatory framework of scientific research in Brazil, although this work has not problematized either, in a specific way, the normalization of researches that do not involve human beings, but whose results have impact on the health of the population.

In view of the above, we retrieve the initial questions pointed out in this work regarding the need to evaluate beforehand such researches, the ethical responsibility of the consequences of those studies, and the search for a balance between the freedom of scientific production and the protection of the health of the population.

It is important to emphasize that, in general, scientific researches are carried out not only due to the benefits that they may bring to the population, but increasingly due to economic and strategic interests (GARRAFA ET AL., 2010); this aspect becomes even more pressing when it involves the pharmaceutical industry and the bellicose power of certain groups of countries, which highlights the need to address the problem from a broader perspective of bioethics.

In order to exemplify the distortions that many times occur with clinical researches,

a field contiguous with the discussion developed hereby, it is important to register a study by Ugalde and Homedes (2011), two Spanish researchers who have been working for many years in the United States. Analyzing clinical studies funded by large multinational pharmaceutical industries in Latin America, they denounce scientific frauds and results manipulation, financial interests disguised as science, and the instrumental use of individuals in social vulnerability condition. The authors demonstrate how the industrial secrecy related to multinational clinical researches becomes more important than the safety of the persons involved, creating a perverse logic that hampers the social control over research activities, in an attempt to conceal data manipulation and severe adverse effects that impact on their subjects. Most clinical studies currently carried out in peripheral countries worldwide give greater importance to financial motivation than to the scientific process itself (LORENZO; GARRAFA, 2011).

In view of this entire context, an essential reference is the Universal Declaration on Bioethics and Human Rights (UDBHR), whose objective is to balance the respect for values such as human dignity, the protection of vulnerations, and scientific freedom, among others. In its Article 20, the document mentions that States should promote “appropriate assessment and adequate management of risks related to medicine, life sciences and associated technologies”, and in Article 24 it mentions that: “States should foster international dissemination of scientific information and encourage the free flow and sharing of scientific and technological knowledge” (UNESCO, 2005). Among the principles presented by UDBHR, one can also highlight Article 4 – Benefit and Harm, which mentions the need to maximize the direct and indirect benefits to patients, research participants and other affected individuals and that any possible harm to such individuals should be

minimized. This indicates that, even when carrying out studies that do not involve human beings as objects, there should be ponder between the risks and possible harm and the expected benefits, not only regarding the subjects directly involved but also the entire population, and humanity as a whole, in the present and in the future.

Conclusion

This work has raised ethical questions related to researches that do not involve human beings, but whose results have impact on the health of the population. The analysis verified that there is an absence of Brazilian norms for the regulation of this kind of research, as well as the incipience of scientific production on this theme. It is surprising that a theme of such immediate relevance for the population and, above all, for the future generations, including the preservation of the planetary environmental balance (depending on the kind of research), has been receiving so little attention from public administration, universities, firms, and even the researchers involved with this issue.

However, it is imperative to register as a limiting factor in the current study that it did not adopt a normative or bibliographic search in the international sphere; this is planned for the future development of the PhD thesis of one of the authors of this study, aiming to evaluate how other countries and international instances have been approaching the problem.

Due to the severity of the impact that certain researches may cause to the health of the population, the preliminary conclusion of this study is that it is necessary to establish in the future ways of ethical control of researches that do not directly involve human beings as the subject of the experiment. For this purpose, it is necessary to initiate, in the different governmental

instances, discussions on research ethics and the responsibility of researchers, institutions, funders, and government regarding the consequences of the results. In this sense, an important normative guidance is UNESCO's Universal Declaration on Bioethics and Human Rights, in that it approaches the relation between scientific advances and the protection of human beings in a broad perspective. However, it is important to refer that as the Declaration is basically a normative document in the international sphere, it is necessary that the suggested norms become legislation with practical application in each country, in order to guarantee the crucial concrete measures for sanitary protection related to the central problem that is the object of this work.

Having come to the conclusion about the

need of ethical control on the specific kind of research addressed in this study, it is also important to analyze how this process will be developed and who will carry out the assessment. The activity of science-making nowadays is loaded with potential ethical implications. Only with joint, responsible and articulated participation of the State, scientists, and society regarding the assessment and decision-making of firm and rigorous content, it will be possible to provide a proper course to this issue.

Colaborators

The three authors participated jointly in the elaboration of this article. ■

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